



International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

3249 '99 SEP 16 10 54

September 10, 1999

Dockets Management Branch
Food and Drug Administration (I-IFS-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 99N-1076

Dear Sir or Madam:

The International Ice Cream Association (IICA) is the trade association for manufacturers, processors, distributors and marketers of ice cream and ice cream related products. Its 145-member companies process approximately 85% of the ice cream and frozen desserts manufactured in the United States and Canada. IICA is one of the constituent organizations of the International Dairy Foods Association along with the Milk Industry Foundation (MIF) and the National Cheese Institute (NCI).

This is in response to FDA's request for scientific data and information to assist in a Risk Assessment of the Public Health Impact of Food-borne **Listeria monocytogenes**. IICA member companies are voluntarily providing "blinded" historical test results for the presence of **Listeria monocytogenes** and **Listeria** (non-species) in finished ice cream and frozen dessert products. This data was compiled from historical test results collected during the years of 1993 through 1998. Some companies provided data for all six years while other companies only had test results available from two years.

Data was collected for five different categories of ice cream and frozen dessert products:

- Packaged ice cream and frozen yogurts with flavorings added before pasteurization
- Packaged ice cream and frozen yogurts with flavorings added after pasteurization
- Sherbet
- Ice cream novelties – sticks, bars, sandwiches, sundae cups, etc.
- Water ice and sorbet – includes packaged products and novelties (that do not contain dairy ingredients)

99N-1076

C3

Attached are summarized data tables for categories of products. It is important to note that the results are broken down in two ways. The first table includes results for *Listeria*, which is not species-specific. Some companies may conduct preliminary testing to determine whether *Listeria* is present, using rapid methods such as ELISA, in order to minimize the time and expense. Additionally, the FDA – BAM methods may be used to provide a presumptive result for *Listeria* but are not carried out to detect the specific species. The second group of data includes results for *Listeria monocytogenes*. Note that some samples were reported as both *Listeria* not specific for species, then re-tested and reported after confirming the *monocytogenes* species.

As summarized in the tables, there is significant information available to demonstrate the extremely infrequent presence of *Listeria species* and *Listeria monocytogenes* specifically in ice cream and frozen novelties. Unfortunately, due to FDA's current "zero tolerance" regulatory policy for *Listeria monocytogenes* in food, there is no need to conduct quantitative analysis on positive samples. Therefore no quantitative data is available that our members can provide to FDA.

Ice cream manufacturers also provided information on the amount of product represented by the test results. It was hoped that this information could be used to determine the percent of ice cream and frozen desserts represented by the results on an annual basis. However, due to results being reported for various time periods, it is not possible to calculate the data by volume on an annual basis. When available, volume data has been compiled as the total amounts of ice cream and frozen desserts represented by the test results for the time period of 2-6 years (1993-1998). The 44,850 samples tested for *Listeria* by ice cream manufactures represents approximately 222,796,799 gallons of ice cream and frozen desserts. The total amount of product represented by the 23,038 samples tested for *Listeria monocytogenes* is estimated at 17,622,050 gallons. This information can be compared to the United States annual production for ice cream and frozen desserts of 1,560,380,000 gallons as reported by the USDA for 1997.

The International Dairy Foods Association and our members support the efforts of FDA in consultation with the USDA Food Safety Inspection Service in conducting a risk assessment to determine the prevalence and exposure of consumers to foodborne *Listeria monocytogenes* and to assess the resulting public health impact of such exposure. There is a clear need to review the current validity of the "zero tolerance" regulatory policy for *Listeria monocytogenes* in ready-to-eat foods. We believe that this comprehensive data on ice cream and frozen desserts provides sound scientific evidence for determining that this product category represents a low risk food and should serve as a foundation for reevaluating the current regulatory policy without posing any increased risk to public health.

Page 3

IDFA appreciates the opportunity to provide scientific data and information to be considered for inclusion in the FDA and USDA/FSIS 's risk assessment for ***Listeria monocytogenes***. Please contact me if you have any additional questions or if further clarification is necessary.

Yours truly,

A handwritten signature in black ink, appearing to read 'Cary P. Frye', written in a cursive style.

Cary P. Frye
Vice President
Scientific & Regulatory Affairs

Attachments

cc: Dr. Richard Whiting
cc: Dr. Mary Bender
cc: Chuck Carrington
cc: Tony Hutchinson

Prevalence of Listeria species (not specific for Listeria monocytogenes)

International Ice Cream Association Summarized Historical Data 1993-I 998

Ice cream and frozen yogurt with flavors added before pasteurization - includes bulk, packaged and single serve cups.

Sample Size	# of Samples	# Positive for	Method	%
25 grams	9	0	FDA-BAM	
Total	9	0		0.00%

Ice cream and frozen yogurt with flavors added after pasteurization - includes bulk, packaged and single serve cups.

Sample Size	# of Samples	# Positive for	Method	%
25 grams	365	0	FDA-BAM	
25 grams	4016	2	Elisa	
7 gallons	15	0	not specified	
1/2 gallon	30	0	USDA	
100 grams	360	0	FDA-BAM	
Total	4786	2		0.04%

Sherbet

Sample Size	# of Samples	# Positive for	Method	%
1 gallon	4	0	not specified	
25 grams	1000	1	Elisa	
Total	1004	1		0.10%

Ice cream novelties - sticks, bars, sandwiches, sundae, cups

Sample Size	# of Samples	# Positive for	Method	%
25 grams	12950	25	Elisa	
2.5 oz. Bar	30	0	USDA	
25 grams	4	0	Gene Trak	
25 grams	149	0	FDA-BAM	
25 g/125 g	2746	4	Elisa	
100 grams	19320	4	FDA-BAM	
Total	35199	33		0.09%

Water ice and sorbet - includes packaged products and novelties that do not contain dairy ingredients.

Sample Size	# of Samples	# Positive for	Method	%
25 grams	32	0	FDA-BAM	
25 grams	1900	0	Elisa	
100 grams	1920	0	FDA-BAM	
Total	3852	0		0.00%

Total ice cream, sherbet, novelties, water ice and sorbet

Sample Size	# of Samples	# Positive for	Method	%
Varies	44850	36	Varies	0.08%

Prevalence of *Listeria monocytogenes*

International Ice Cream Association Summarized Historical Data 1993-I 998

Ice cream and frozen yogurt flavorings added before pasteurization - includes bulk, packaged and single serve cups

Sample Size	# of Samples Tested	# Positive for <i>Listeria</i>	Method	%
25 grams	10	0	FDA-BAM	
Total	10	0		0.00%

Ice cream and frozen yogurt flavorings added after pasteurization - includes bulk, packaged and single serve cups

Sample Size	# of Samples Tested	# Positive for <i>Listeria</i>	Method	%
25 grams	15	0	FDA-BAM	
1/2 gallon	132	0	USDA	
100 grams *	360	0	FDA-BAM	
Total	507	0		0.00%

*Retested for monocytogenese , also reported as *Listeria* species

Ice cream novelties - sticks, bars, sandwiches, sundae, cups

Sample Size	# of Samples Tested	# Positive for <i>Listeria</i>	Method	%
25 grams *	350	3	FDA-BAM	
2.5 oz. Bar	30	0	USDA	
25 grams	877	28	FDA-BAM	
100 grams*	19320	9	FDA-BAM	
Total	20577	40		0.19%

*Retested for monocytogenese , also reported as *Listeria* species

Water ice and sorbet - includes packaged products and novelties (that do not contain dairy ingredients)

Sample Size	# of Samples Tested	# Positive for <i>Listeria</i>	Method	%
25 grams *	24	0	FDA-BAM	
100 grams*	1920	0	FDA-BAM	
Total	1944	0		0.00%

*Retested for monocytogenese , also reported as *Listeria* species

Total ice cream, sherbet, novelties, water ice and sorbet

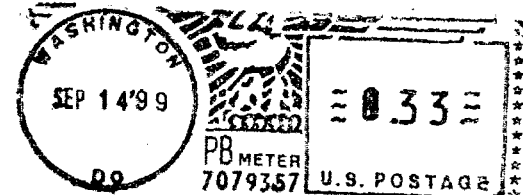
Sample Size	# of Samples Tested	# Positive for <i>Listeria</i>	Method	%
Varies	23038	40	Varies	0.17%



International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

1250 H St., NW, Suite 900
Washington, DC 20005

151000



Dockets Management Branch
Food and Drug Administration (HFS-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

